REMARKS

Claims 1-30 and 35-61 are pending in the application. Claims 31-34 were canceled without prejudice. Claims 1, 2, 12 and 18-23 are withdrawn from consideration in response to a Restriction Requirement. By this amendment, claims 3, 15, 24, and 50 are amended for clarity in accordance with the Office's suggestions. All amendments herein are fully supported by the disclosure and no new matter has been added to the application.

Claim Objections

Claim 55 is objected to because the subject claim is asserted to be a duplicate of claim 54. Applicants respectfully note that claim 54 recites that the subject glycol derivative is propylene glycol, whereas claim 55 recites that the subject glycol derivative is polyethelyene glycol. Accordingly, the claims are not duplicative and no correction is believed to be required.

Double Patenting

Claims 36 and 47-49 are provisionally rejected for alleged obviousness-type double patenting over claims 1-3 of U.S. Patent No. 6,436,950 B1. The Office acknowledges that the subject claims are not identical, but asserts that they are not patentably distinct from each other because they are allegedly drawn to the same technical fields, with the same active agents, same reducing agents, and same pH value.

Claims 41-44, 50 and 52-57 are provisionally rejected for alleged obviousness-type double patenting over claims 1-7 of copending Application No. 09/665,500. The Office acknowledges that the subject claims are not identical, but asserts that they are not patentably distinct from each other because they are allegedly drawn to the same technical fields, active agents, and solubilizing agents.

Claims 24-28 are provisionally rejected for alleged obviousness-type double patenting over claims 21-32 and 39 of copending Application No. 09/882,746. The Office acknowledges that the subject claims are not identical, but asserts that they are not patentably distinct from each other because they are allegedly drawn to the same technical fields, composition, active agents, and onset of action.

Claims 3, 39, 47-49, 50, 51 and 59-61 are provisionally rejected for alleged obviousness-type double patenting over claims 62, 71 and 73 of copending Application No.10/062,021 and claims 62-71 of copending Application No. 10/062,020. The Office acknowledges that the subject claims are not identical, but asserts that they are not patentably distinct from each other because they are allegedly drawn to the same technical fields, composition, active agents, and mechanism of action.

Applicants acknowledge each of the foregoing rejections for alleged double patenting. Applicants will review the subject claims of the respective applications and evaluate the merits of the asserted double patenting rejections. Upon indication of allowable subject matter in one of the asserted conflicting applications, Applicants will take any necessary action to ensure that validly conflicting subject matter is not maintained in both applications.

***Patentability Under* 35 *USC* § 102**

Claims 3-5, 13, 24-29 are rejected under 35 U.S.C. 102(b) as allegedly anticipated by Cicinelli et al. (1996) in view of American Hospital Formulary Service (1988) and Heaton et al. (1995).

With regard to claim 3, Cicinelli et al. is cited for allegedly teaching a dopamine receptor agonist (bromocriptine) in a nasal spray composition.

American Hospital Formulary Service on page 2133, left-hand side, under Chemistry and Stability, is relied upon for allegedly teaching that bromocriptine is a dopamine receptor agonist.

With regard to claims 3-5 and 13, 24-29, Heaton et al. is cited for allegedly teaching an aqueous nasal spray apomorphine preparation.

As a preliminary matter, Applicants dispute the Office's general assertion made in support of the foregoing rejection with respect to intended use (e.g., in claim 3) and onset of action (e.g., claims 24-29). Specifically, the Office asserts that, even though the prior art fails to disclose these properties, they cannot provide a "patentable limitation" because they do not impart a "physical limitation to the composition that is not found in the prior art composition."

Contrary to the Office's interpretation, Applicants claims recite specific functional limitations that correlate with distinct "physical limitations" not found in the prior art of record. It is well established law that functional and use limitations are fully permissible to distinguish compounds and compositions from prior art compounds and compositions lacking the specified functional and/or use characteristics. In the case of functional limitations to claim a species or class of compounds apart from other members of a broader class--all that is required is that terms reciting a novel use or property of a composition must "define, indirectly at least, some characteristic not found in the old composition" In re Pearson, 181 USPQ 641 (CCPA 1974). This law correlates with other decisions that allow for patenting of old compounds for new uses.

In the instant case, the Office relies on three references to support the rejection under 35 U.S.C. § 102. Ordinarily, anticipation requires every element in the rejected claim to be disclosed in a single reference. Continental Can Co. USA v. Monsanto Co., 20 USPQ2d (Fed. Cir. 1991). The Federal Circuit in Continental Can explained that secondary references can be used to show "an inherent feature" of the subject matter disclosed in the cited reference, but with the following express limitations:

> Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.

In the instant case, the independent claims recite a pharmaceutical composition for treating sexual dysfunction in a mammal comprising a therapeutically effective amount of "a dopamine receptor agonist that exhibits activity for alleviating said sexual dysfunction . . ." The formulations are each specified as an aqueous formulation suitable for intranasal delivery. Additionally, as recited in independent claim 3, the "pharmaceutical composition is intransally effective to alleviate said sexual dysfunction without causing substantial intolerable adverse side effects in said mammal."

The claims thus present a number of use/function elements or limitations that distinguish the claimed compounds and compositions from the prior art compounds and compositions. Concerning the disclosure of Cicinelli et al., the subject compound (bromocriptine) may be broadly characterizable as a dopamine receptor agonists, but it is more specifically a synthetic derivative of the ergotoxin group of ergot alkaloids. As

noted in the secondary reference, American Hospital Formulary Service (on page 2133, left-hand side), bromocriptine exhibits a known activity of "inhibiting release of prolactin from the anterior pituitary." The subject group of compounds exemplified by bromocriptine is therefore believed to be contraindicated in the presently claimed formulations for treating sexual dysfunction. Certainly, there is no evidence provided in either the Cicinelli et al. or American Hospital Formulary Service references that bromocriptine mesylate, or any other dopamine receptor agonist, will expressly or inherently possess the instantly claimed functional and use properties, as summarized above. Stated alternatively, the evidence of record does not establish that each limitation recited in the instant claims "is necessarily present" in one or all of the cited references, and "would be so recognized by persons of ordinary skill". On the contrary, the art of record clearly fails to disclose or suggest Applicants' effective use of "a dopamine receptor agonist that exhibits activity for alleviating . . . sexual dysfunction . . ." in "an aqueous formulation suitable for intranasal delivery", wherein the "pharmaceutical composition is intransally effective to alleviate said sexual dysfunction without causing substantial intolerable adverse side effects in said mammal."

With respect to the teachings of Heaton et al. (1995), this reference clearly fails to disclose the subject matter of Applicants' invention, and instead teaches directly away from the instantly claimed compositions and dosage forms. As expressly described by Heaton and colleagues, various "unmodified", simple, "aqueous" formulations of apomorphine were tested in human male patients with sexual dysfunction. All such "unmodified" formulations were reported to be "associated with unacceptable adverse side effects" (p. 202, right column, p. 205, left column). In two patients treated with the low dose, intranasal spray:

> [B]oth experienced significant adverse effects (yawning, nausea, vomiting dizziness, blurred vision, diaphoresis, pallor, mild hypotension, and bradycardia with an onset within 5 minutes and lasting up to 15 minutes). No further attempts were made to test this preparation or route of administration. (p. 203, right column).

Apparently the same study results are presented in El-Rashidy et al. U.S. Patent No. 5,770,606 ('606 patent) (of record--both publications include El-Rashidy and Heaton

as authors/inventors), which clarifies that an aqueous, 2.5 mg intranasal dose of apomorphine elicited unacceptable side effects including yawning and "major hemodynamic adverse effects", pale and ashen coloring, diaphoresis, nausea and vomiting, blurred vision, hypotension with a blood pressure of 70/50 . . .." (column 9, lines 4-25).

In light of these findings, the principal conclusion by Heaton et al. was that "unmodified" (i.e., simple aqueous) apomorphine dosage forms yield unacceptable adverse side effects, which are considered severe even in the case of low dose intranasal sprays. On this basis, and in view of other previous studies, the authors considered such formulations and dosage forms to be inoperable—and set forth a distinct goal for developing sublingual, controlled release apomorphine formulations, as follows:

> The primary goal was to develop a formulation that permitted controlled release, achieving and adequate therapeutic response without side effects. (p. 201, left column, underscore added).

This undertaking led to the development of a reportedly effective sublingual delivery method for apomorphine "formulated for controlled absorption." (See Heaton et al., Abstract), which is generally the same subject presented in the '606 patent. This same approach was adopted in the presently cited reference by Illum et al., (WO 99/27905), wherein the following assertions are made in an attempt to distinguish the disclosed invention over the prior art (particularly Heaton et al.);

> Thus, the prior art teaches that the nasal delivery of most drugs for the treatment of erectile dysfunction tends to be associated with unacceptable side effects. (p. 5, lines 4-6). . . . [A] simple nasal spray containing such a drug is an unsatisfactory dosage form since it provides a high peak level of the drug in the blood initially followed by a rapid decline in this level leading to adverse reactions and poor efficacy. (p. 6, lines 25-28). The reduction of the plasma level-time profile in order to minimize side effects and adverse reactions for drugs used in the treatment of erectile dysfunction such as apomorphine is neither mentioned nor suggested. . . .. (p. 4, lines 17-20). Controlled release nasal formulations for the treatment of erectile dysfunction have not been described previously. (p. 5, lines 8-9, emphasis supplied).

Considering the foregoing evidence, Heaton et al. clearly fails to anticipate the subject matter of Applicants claimed invention. Moreover, Heaton et al. actually emphasizes, rather than cures, the deficiencies of the other cited references, Cicinelli et al., and American Hospital Formulary Service. For these reasons, the rejection of claims 3-5, 13, 24-29 under 35 U.S.C. 102(b) is believed to be overcome.

***Patentability Under* 35 *USC* § 102**

Claims 3, 39, 41-44, 46, 50, 52-58 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Azria et al. (U.S.Patent No.4758423) in view of DRUG FACTS AND COMPARISONS (1997). Azria et al. is cited for allegedly teaching a pharmaceutically acceptable nasal spray comprising bromocriptine, polyethylene glycol, and propylene glycol. DRUG FACTS AND COMPARISONS on page 3507 lines 1-8, is cited for allegedly teaching that bromocriptine is a dopamine receptor agonist.

The Office asserts that one of ordinary skill in the art would have been "motivated to formulate bromocriptine nasal spray comprising the specified glycol derivatives" since Azria et al. teach that any glycol especially propylene glycol and polyethylene glycol are useful in formulating nasal bromocriptine/nasal liquid spray. In addition, the surfactants and other additives (glycerin) set forth in Applicants dependent claims are deemed obvious since they are alleged to "represent conventional formulations."

Applicants respectfully traverse the stated grounds for rejection under 35 U.S.C. 103(a) and submit that the subject matter of claims 3, 39, 41-44, 46, 50, 52-58 is neither disclosed nor suggested by the combined teachings of Azria et al. in view of DRUG FACTS AND COMPARISONS.

As noted above, the independent claims recite a pharmaceutical composition for treating sexual dysfunction in a mammal comprising a therapeutically effective amount of "a dopamine receptor agonist that exhibits activity for alleviating said sexual dysfunction . . ." The invention is further directed to an aqueous formulation suitable for intranasal delivery. Additionally, the "pharmaceutical composition is intransally effective to alleviate said sexual dysfunction without causing substantial intolerable adverse side effects in said mammal."

Concerning the disclosure of Azria et al., this reference is considered comparable in significance to the disclosure of Cicinelli et al., addressed above. Although the subject

compound (bromocriptine) may be broadly characterizable as a dopamine receptor agonists, it is more specifically an ergotoxin. The disclosed function of this compound for "inhibiting release of prolactin from the anterior pituitary" American Hospital Formulary Service (on page 2133, left-hand side) is believed to be contraindicated in the presently claimed formulations for treating sexual dysfunction. Clearly, neither the Cicinelli et al. nor DRUG FACTS AND COMPARISONS discloses that bromocriptine mesylate, or any other dopamine receptor agonist, will expressly or inherently possess the instantly claimed functional and use properties.

In view of the foregoing, and further considering the factual discussion presented above pertaining to patentability under 35 U.S.C. § 102, the art of record, viewed as a whole, fails to teach or suggest Applicants' effective use of "a dopamine receptor agonist that exhibits activity for alleviating . . . sexual dysfunction . . ." in "an aqueous formulation suitable for intranasal delivery", wherein the "pharmaceutical composition is intransally effective to alleviate said sexual dysfunction without causing substantial intolerable adverse side effects in said mammal."

This conclusion is underscored by the above-cited article by Heaton et al. (1995), which teaches directly away from the presently claimed formulations. Specifically, the Heaton et al. reference teaches that "unmodified", simple, "aqueous" formulations of apomorphine were "associated with unacceptable adverse side effects" (p. 202, right column, p. 205, left column). In two patients treated with the low dose, intranasal spray:

> [B]oth experienced significant adverse effects (yawning, nausea, vomiting dizziness, blurred vision, diaphoresis, pallor, mild hypotension, and bradycardia with an onset within 5 minutes and lasting up to 15 minutes). No further attempts were made to test this preparation or route of administration. (p. 203, right column).

In view of the foregoing, Applicants respectfully request that the rejection of claims 3, 39, 41-44, 46, 50, 52-58 under 35 U.S.C. 103(a) over Azria et al. in view of DRUG FACTS AND COMPARISONS be withdrawn. Applicants do not accede to the alleged teachings of these references with respect to the numerous detailed aspects of the invention set forth in the dependent claims, as asserted by the Office.

Claims 3-11, 13-17, 24-30, and 35-61 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Illum (WO 99/27905) in view of Merkus (U.S. Patent No. 5, 756,483) and further view of El-Rashidy et al. (U.S.Patent No. 5,888,534). Illum is cited as the primary reference for allegedly teaching a composition for nasal administration of apomorphine or salt thereof, for treating erectile dysfunction in a mammal. In addition, Illum allegedly teaches that the above composition minimizes side effects and adverse reactions unlike other nasal formulation of apomorphine. In dependent aspects, Illum is cited for allegedly disclosing that apomorphine compositions can be employed with a variety of excipient, comprising carboxymethyl cellulose, with a buffer system in a liquid composition, other pharmacologically-acceptable, non-toxic ingredients such as preservatives, and appropriate buffers within applicants' range as set forth in claim 36.

El-Rashidy et al. is cited secondarily for allegedly teaching that polyethylene glycol and glycerin are suitable components of apomorphine formulation. El-Rashidy et al. is further cited for allegedly teaching a sublingual apomorphine formulation containing sugar alcohol (mannitol), and stabilizing agent (ascorbic acid, glycerin, polyethylene glycol).

Merkus is cited for allegedly teaching various formulations of apomorphine containing sodium metabisulfite, water, propylene glycol, methylcellulose, surgar alcohol (sorbitol) and derivatives. Merkus is further cited for allegedly teaching that intranasal formulations of apomorphine can be formulated with many other excipients, such as preservatives, surfactant, co-solvents, adhesives, antioxidants, buffers, viscosity enhancing agents and agents to adjust the pH or the osmolarity.

The Office asserts that it would have been obvious to modify the primary apomorphine composition of Illum to include other pharmaceutically acceptable excipients and non-toxic ingredients, and any appropriate buffers formulated with apomorphine.

Applicants respectfully traverse the stated grounds for rejection under 35 U.S.C. 103(a) and submit that the subject matter of the instant invention is neither disclosed nor suggested by the combined teachings of Illum, Merkus, and El-Rashidy.

Applicants respectfully submit that the primary, Illum et al. reference fails to qualify as prior art against the instant claims. In this regard, Applicants note that the

present application duly claims priority as a continuation of U.S. Application Serial No. 09/334,304 (now U.S. Patent No. 6,436,950 B1, issued August 20, 2002) filed June 16, 1999, which in turn claims the benefit of U.S. Provisional Application No. 60/096,545, filed August 14, 1998. The Illum et al. reference (corresponding to PCT/GB98/03572, filed November 27, 1998), has an international publication date of June 10, 1999. A corresponding U.S. patent (U.S. Patent No. 6,342,251 B1) was filed June 2, 2000. Accordingly, the effective prior art date of the Illum et al. reference is respectfully submitted to be after the effective priority date of the instantly claimed subject matter.

Because Illum is not believed to properly serve as a primary reference as cited, the subject rejection of claims under 35 U.S.C. § 103 is believed to be obviated. Further, each of the secondary references is deficient for the reasons noted above. Applicants do not accede to the alleged teachings of these references with respect to more specific aspects of the invention set forth in the dependent claims, as asserted by the Office. Collectively, it is believed that the art of record underscores the need in the art for Applicants' invention, and the unexpected nature of the subject technology as claimed. Withdrawal of the rejection of claims 3-11, 13-17, 24-30, and 35-61 under 35 U.S.C. 103(a) over Illum in view of Merkus and El-Rashidy et al. is therefore earnestly solicited.

CONCLUSION

In view of the foregoing, Applicants believe that all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version With Markings To Show Changes Made."

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 425-455-5575.

Respectfully submitted,

Date: May 5, 2003

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Withdrawn/Previously Amended) A method of ameliorating sexual dysfunction in a mammal comprising nasally administering a therapeutically effective amount of a dopamine receptor agonist in an aqueous formulation for intranasal delivery to said mammal before, during or after sexual activity which is intranasally effective to alleviate said sexual dysfunction without causing substantial intolerable adverse side effects to said mammal.

2. (Withdrawn) The method of Claim 1, wherein said dopamine receptor agonist is selected from the group consisting of apomorphine, chemically modified equivalents and pharmaceutical salts thereof.

3. (Currently and PreviouslyAmended) A pharmaceutical composition for treating sexual dysfunction in a mammal comprising a therapeutically effective amount of a dopamine receptor agonist <u>that exhibits activity for alleviating said sexual dysfunction</u> in an aqueous formulation for intranasal delivery, wherein said pharmaceutical composition is intransally effective to alleviate said sexual dysfunction without causing substantial intolerable adverse side effects in said mammal.

4. (Original) The pharmaceutical composition of Claim 3, wherein said dopamine receptor agonist is apomorphine.

5. (Previously Amended) The pharmaceutical composition of Claim 4, wherein said apomorphine is dispersed in an aqueous spray formulation.

6. (Previously Amended) The pharmaceutical composition of Claim 4, wherein said aqueous formulation for intranasal delivery comprises a buffer to maintain the pH of said dopamine receptor agonist, a pharmaceutically acceptable thickening agent and a humectant.

7. (Original) The pharmaceutical composition of Claim 6, further comprising one or more pharmaceutical excipients.

8. (Original) The pharmaceutical composition of Claim 7, further comprising a pharmaceutically acceptable preservative.

9. (Original) The pharmaceutical composition of Claim 6, wherein said buffer is selected from the group consisting of acetate, citrate, prolamine, carbonate and phosphate buffers.

10. (Original) The pharmaceutical composition of Claim 6, wherein said thickening agent is selected from the group consisting of methyl cellulose, xanthan gum, carboxymethyl cellulose, hydroxypropyl cellulose, carbomer, polyvinyl alcohol, alginates, acacia, chitosans and combinations thereof.

11. (Original) The pharmaceutical composition of Claim 6, wherein said humectant is selected from the group consisting of sorbitol, glycerol, mineral oil, vegetable oil and combinations thereof.

12. (Withdrawn) A method of treating erectile dysfunction in a male mammal comprising nasally administering the composition according to Claim 3.

13. (Original) The pharmaceutical composition of Claim 3, wherein said dopamine receptor agonist is selected from the group consisting of apomorphine, chemically modified equivalents and pharmaceutical salts thereof.

14. (Original) The pharmaceutical composition of Claim 13, wherein said chemically modified equivalents comprise a pro-drug.

15. (Currently and Previously Amended) A pharmaceutical composition for treating male or female sexual dysfunction in a mammalian subject comprising a therapeutically effective amount of a dopamine receptor agonist <u>that exhibits activity for alleviating said sexual dysfunction</u> dispersed in an aqueous formulation for intranasal delivery comprising a buffer to maintain a pH of the formulation, a pharmaceutically acceptable thickening agent and a humectant, wherein said pharmaceutical composition is intransally effective to alleviate said sexual dysfunction and does not cause substantial intolerable adverse side effects when administered to said mammal.

16. (Previously Amended) The pharmaceutical composition of Claim 15, wherein said dopamine receptor agonist is selected from the group including apomorphine, chemically modified equivalents and pharmaceutical salts thereof.

17. (Previously Amended) The pharmaceutical composition of Claim 16, wherein said chemically modified equivalents comprise a pro-drug.

18. (Withdrawn) A method of treating impotence and male erectile dysfunction in a human in need of such treatment comprising administering to a nasal membrane of said human an effective amount of a composition according to Claim 15.

19. (Withdrawn) A method of treating male erectile without causing substantial intolerable adverse side effects in a mammal comprising administering into a nasal cavity of said mammal a therapeutically effective dosage of a dopamine receptor agonist in combination with a nasal delivery system comprising a pharmaceutically acceptable buffer, a thickening agent and a humectant.

20. (Withdrawn) The method of Claim 19, wherein said dopamine receptor agonist is selected from the group consisting of apomorphine, chemically modified equivalents and pharmaceutical salts thereof.

21. (Withdrawn) The method of Claim 20, wherein said chemically modified equivalents comprise a pro-drug.

22. (Withdrawn/Previously Amended) A method of administering a therapeutically effective amount of a dopamine receptor agonist to a mammal through a nasal membrane thereof for treatment of male or female sexual dysfunction in said mammal comprising delivering to said nasal membrane a therapeutically effective amount of said dopamine receptor agonist which does not cause substantial intolerable adverse side effects in said mammal, wherein said dopamine receptor agonist is dispersed in an aqueous formulation for intranasal delivery comprising a pharmaceutically acceptable a buffer, a thickening agent and a humectant.

23. (Withdrawn) The method of Claim 22, wherein said dopamine receptor agonist is effective for the treatment of male erectile dysfunction in a mammal.

24. (Currently and Previously Amended) An intranasal dosage unit for treating impotency or erectile dysfunction in a mammal comprising an effective amount of a dopamine receptor agonist that exhibits activity for treating said impotency or erectile dysfunction in an aqueous formulation for intranasal delivery comprising a buffer, wherein said dosage unit does not cause substantial intolerable adverse side effects in said mammal and an erection is produced in said mammal within about 60 minutes of administering said dosage unit to a nasal mucosa of said mammal.

25. (Original) The intranasal dosage unit of Claim 24, wherein said erection is produced within about 45 minutes.

26. (Original) The intranasal dosage unit of Claim 24, wherein said erection is produced within about 30 minutes.

27. (Original) The intranasal dosage unit of Claim 24, wherein said erection is produced within about 15 minutes.

28. (Original) The intranasal dosage unit of Claim 24, wherein said erection is produced in less than about 15 minutes.

29. (Previously Amended) The intranasal dosage unit of Claim 24, wherein said aqueous formulation is administered to said mammal as an aqueous spray.

30. (Previously Amended) The intranasal dosage unit of Claim 29, wherein said aqueous formulation is selected from the group consisting of aqueous gels, aqueous suspensions, aqueous liposomal dispersions, aqueous emulsions, aqueous microemulsions and combinations thereof.

31. (Canceled) The intranasal dosage unit of Claim 24, wherein said intranasal carrier is a non-aqueous solution.

32. (Canceled) The intranasal dosage unit of Claim 31, wherein said non-aqueous solution is selected from the group consisting of non-aqueous gels, non-aqueous suspensions, non-aqueous liposomal dispersions, non-aqueous emulsions, non-aqueous microemulsions and combinations thereof.

33. (Canceled) The intranasal dosage unit of Claim 24, wherein said intranasal carrier is a powder formulation.

34. (Canceled) The intranasal dosage unit of Claim 33, wherein said powder formulation is selected from the group consisting of simple powder mixtures, powder microspheres, coated powder microspheres, ribosomes and combinations thereof.

35. (Original) The intranasal dosage unit of Claim 24, further comprising an excipient having bio-adhesive properties.

36. (Previously Amended) The intranasal dosage unit of Claim 24, wherein said buffer is selected to have a pH of from about 3 to about 3.5.

37. (Original) The intranasal dosage unit of Claim 24, further comprising a humectant.

38. (Original) The intranasal dosage unit of Claim 37, wherein said humectant is selected from the group consisting of soothing agents, membrane conditioners, sweeteners and combinations thereof.

39. (Previously Amended) A pharmaceutical composition according to claim 3, wherein said dopamine receptor agonist [which] has been dispersed with a solubilizing agent to improve its solubility.

40. (Previously Amended) The pharmaceutical composition of Claim 39, wherein said dopamine receptor agonist is selected from the group consisting of apomorphine, chemically modified equivalents and pharmaceutical salts thereof.

41. (Previously Amended) The pharmaceutical composition of Claim 39, wherein said system comprises glycerin.

42. (Previously Amended) The pharmaceutical composition of Claim 39, wherein said solubilizing agent comprises a glycol derivative.

43. (Previously Amended) The pharmaceutical composition of Claim 42, wherein said glycol derivative is propylene glycol.

44. (Previously Amended) The pharmaceutical composition of Claim 42, wherein said glycol derivative is polyethylene glycol.

45. (Previously Amended) The pharmaceutical composition of Claim 39, wherein said [system] solubilizing agent comprises a sugar alcohol.

46. (Previously Amended) The pharmaceutical composition of Claim 39, wherein said solubilizing agent comprises propylene glycol and glycerin.

47. (Previously Amended) The pharmaceutical composition of Claim 39, wherein said solubilizing agent comprises ascorbic acid and water.

48. (Previously Amended) The pharmaceutical composition of Claim 39, wherein said solubilizing agent comprises sodium ascorbate and water.

49. (Previously Amended) The pharmaceutical composition of Claim 39, wherein said solubilizing agent comprises sodium metabisulfite and water.

50. (Currently and Previously Amended) A pharmaceutical composition for treating male erectile dysfunction in a mammal comprising a therapeutically effective amount of a dopamine receptor agonist that exhibits activity for treating said male erectile dysfunction which has been dispersed in an aqueous formulation for intranasal delivery comprising a stabilizing agent to improve stability of said dopamine receptor agonist in the formulation.

51. (Previously Amended) The pharmaceutical composition of Claim 50, wherein said dopamine receptor agonist is selected from the group consisting of apomorphine, chemically modified equivalents and pharmaceutical salts thereof.

52. (Previously Amended) The pharmaceutical composition of Claim 50, wherein said stabilizing agent comprises glycerin.

53. (Previously Amended) The pharmaceutical composition of Claim 50, wherein said stabilizing agent comprises a glycol derivative.

54. (Previously Amended) The pharmaceutical composition of Claim 53, wherein said glycol derivative is propylene glycol.

55. (Previously Amended) The pharmaceutical composition of Claim 53, wherein said glycol derivative is polyethylene glycol.

56. (Previously Amended) The pharmaceutical composition of Claim 50, wherein said stabilizing agent comprises a sugar alcohol.

57. (Previously Amended) The pharmaceutical composition of Claim 50, wherein said stabilizing agent comprises propylene glycol and glycerin.

58. (Previously Amended) The pharmaceutical composition of Claim 50, wherein said stabilizing agent comprises polyethylene glycol 400.

59. (Previously Amended) The pharmaceutical composition of Claim 50, wherein said stabilizing agent comprises ascorbic acid and water.

60. (Previously Amended) The pharmaceutical composition of Claim 50, wherein said stabilizing agent comprises sodium ascorbate and water.

61. (Previously Amended) The pharmaceutical composition of Claim 50, wherein said stabilizing agent comprises sodium metabisulfite and water.